

- II. Claims 6-9, drawn to antisense RNA, classified in class 514, subclass 44.
- III. Claims 10-11, drawn to bovine leptin, classified in class 530, subclass 350, for example.
- IV. Claim 12, drawn to an antibody; classified in class 530, subclass 387.1, for example.

Despite the Examiner's comments, the Examiner has not established an adequate basis for forcing an election between the inventions of Groups I, II, III, and IV. The Examiner's restriction requirement is erroneous and should be withdrawn because the Examiner fails to make a *prima facie* case that the search and examination of the entire application would be unduly burdensome. This failure stems from the Examiner's erroneous classifications of at least three of the inventions of Groups I, II, III, and IV.

Nonetheless, as required by the Examiner, Applicant hereby elects that portion of the present invention the Examiner has placed in Group I, with traverse, for prosecution in the above-identified application, in the event the Examiner does not withdraw the present restriction requirement under 35 U.S.C. 121. As noted above, the Examiner has placed claims 1-5 in Group I that Applicant elects for prosecution.

The Basis For Restriction

According to Section 803 of the Manual of Patent Examining Procedure (MPEP), restriction between two or more claimed inventions is only proper where (1) the inventions are either independent or distinct and (2) a search covering the multiple inventions would be a serious burden on the Examiner:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP §§ 806.04 - §§ 806.04(i)) or distinct (MPEP §§ 806.05 - §§ 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

MPEP: First revision (February, 2003) of the 8th Edition (August, 2001).

Evidence supporting an allegation of serious search burden on the Examiner may be supplied as follows:

For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP §§ 808.02.

That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria is set forth in MPEP §§ 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP §§ 806.04(a) - §§ 806.04(i) and §§ 808.01(a).

MPEP, §803. First revision (February, 2003) of the 8th Edition (August, 2001).

The Examiner first alleges that claims 1-5 of Group I are “drawn to DNA encoding bovine leptin, vectors, and host cells, classified in at least class 435, subclass 69.1, for example.”

Subclass 69.1 depends from Subclass 41 of Class 435. The title of Subclass 41 is:

MICRO-ORGANISM, TISSUE CELL CULTURE OR ENZYME
USING **PROCESS** TO SYNTHESIZE A DESIRED CHEMICAL
COMPOUND OR COMPOSITION

U.S. Patent Office Classification Index: March, 2002 (emphasis added). Thus, Subclass 41 concerns a **PROCESS** that uses a “MICRO-ORGANISM, TISSUE CELL CULTURE OR ENZYME” to “SYNTHESIZE A DESIRED CHEMICAL COMPOUND OR COMPOSITION.” Next, the title of Subclass 61.9 of Subclass 41 is:

Recombinant DNA **technique** included in method of making a protein or polypeptide.

Subclass 61.9 of Subclass 41 of Class 435 concerns a **technique** of producing Recombinant DNA, where the **technique** of producing Recombinant DNA is “included in [a] method of making a protein or polypeptide.”

As noted above, the Examiner agrees that claims 1-5 of Group I are “drawn to DNA encoding bovine leptin, vectors, and host cells.” However, claims 1-5 of Group I are not properly classified in Subclass 61.9 of Subclass 41 of Class 435, since Subclass 61.9 concerns a **technique** of producing Recombinant DNA and Subclass 41 concerns a **PROCESS** that uses a “MICRO-ORGANISM, TISSUE CELL CULTURE OR ENZYME” to “SYNTHESIZE A DESIRED CHEMICAL COMPOUND OR COMPOSITION,” while claims 1-5 of Group I define “DNA encoding bovine leptin, vectors, and host cells” and not methods or techniques used to produce “DNA encoding bovine leptin, vectors, and host cells.”

The Examiner next alleges that claims 6-9 of Group II are “drawn to antisense RNA, classified in class 514, subclass 44.” Subclass 44 depends from subclass 43, which depends from subclass 42, which depends from subclass 23, which depends from subclass 1 of Class 514. The title of Subclass 1 is:

DESIGNATED ORGANIC ACTIVE INGREDIENT CONTAINING (DOAI)

U.S. Patent Office Classification Index: March, 2002 (emphasis added). Next, the title of Subclass 23 of Subclass 1 of Class 514 is:

Carbohydrate (i.e., saccharide radical containing) DOAI.

Next, the title of Subclass 42 of subclass 23 of Subclass 1 of Class 514 is:

N-glycoside

Next, the title of Subclass 43 of Subclass 42 of Subclass of Subclass 1 of Class 514 is:

Nitrogen containing hetero ring

Finally, the title of Subclass 44 of Subclass 43 of Subclass 42 of Subclass of Subclass 1 of Class 514 is:

Polynucleotide (e.g., RNA, DNA, etc.)

Thus, Subclass 44 of Subclass 43 of Subclass 42 of Subclass of Subclass 1 of Class 514 concerns a carbohydrate designated organic active ingredient that includes a polynucleotide (e.g., RNA, DNA, etc.).

As noted above, the Examiner agrees that claims 6-9 of Group II are “drawn to antisense RNA.” However, claims 6-9 of Group II are not properly classified in Subclass 44 of Subclass 43 of Subclass 42 of Subclass of Subclass 1 of Class 514, since Subclass 1 concerns a

carbohydrate designated organic active ingredient, while claims 6-9 of Group II define antisense RNA” and make no mention of the carbohydrate required by Subclass 1 of Class 514 (and likewise required by Subclass 44 of Subclass 43 of Subclass 42 of Subclass of Subclass 1 of Class 514).

The Examiner next alleges that claims 10-11 of Group III are “drawn to bovine leptin, classified in class 530, subclass 350, for example.” The title of Subclass 350 of Class 530 is:

PROTEINS, I.E., MORE THAN 100 AMINO ACID RESIDUES

U.S. Patent Office Classification Index: March, 2002. Applicant agrees with the Examiner’s characterization that claims 10-11 of Group III are “drawn to bovine leptin, classified in class 530, subclass 350”

Finally, the Examiner alleges that claim 12 of Group IV is “drawn to an antibody; classified in class 530, subclass 387.1, for example.” Subclass 387.1 depends from Subclass 386, which depends from Subclass 380, which depends from Subclass 350 of Class 530. The title of Subclass 350 of Class 530 is:

PROTEINS, I.E., MORE THAN 100 AMINO ACID RESIDUES

U.S. Patent Office Classification Index: March, 2002. Next, the title of Subclass 380 of Subclass 350 of Class 530 is:

Blood proteins or globulins, e.g., proteoglycans, platelet factor 4, thyroglobulin, thyroxine, etc.

Thus, Subclass 380 of Subclass 350 of Class 530 concerns proteins and globulins of blood. Next, the title of Subclass 386 of Subclass 380 of Subclass 350 of Class 530 is:

Globulins

Thus, Subclass 386 of Subclass 380 of Subclass 350 of Class 530 concerns globulins of blood. Finally, the title of Subclass 387.1 of Subclass 386 of Subclass 380 of Subclass 350 of Class 530 is:

Immunoglobulin, antibody, or fragment thereof, other than immunoglobulin[,] antibody, or fragment thereof that is conjugated or absorbed.

Thus, Subclass 387 of Subclass 386 of Subclass 380 of Subclass 350 of Class 530 concerns blood immunoglobulins, blood antibodies, and fragments thereof (other than blood immunoglobulins blood antibodies, and fragments thereof that are conjugated or absorbed).

As noted above, the Examiner agrees that claim 12 of Group IV is "drawn to an antibody." However, claim 12 of Group IV is not properly classified in Subclass 387 of Subclass 386 of Subclass 380 of Subclass 350 of Class 530, since Subclass 387 concerns a blood immunoglobulins, blood antibodies, and fragments thereof, while claim 12 of Group I defines an antibody" and makes no mention of the **blood antibody** required by Subclass 387 of Class 530.

CONCLUSION

The Examiner has not demonstrated the inventions of Groups I, II, III, and IV are separately classified in the art and has therefor not established by *prima facie* evidence that search and examination of the entire application would impose a serious burden on the Examiner. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement between the inventions of Groups I, II, III, and IV. Nonetheless, as required by the Examiner, Applicant elects that portion of the present invention the Examiner has placed in Group I (claims 1-5), with traverse, for prosecution in the above-identified application, in the event the Examiner does not withdraw the present restriction requirement under 35 U.S.C. 121.

Respectfully submitted,

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